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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,427

09/05/2003

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EXAMINER

VAKILI, ZOHREH

ART UNIT

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1614

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/656,427	Applicant(s) KANE, MICHAEL	
	Examiner ZOHREH VAKILI	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-4 are presented for examination.

Applicant's Amendment filed March 17, 2008 has been received and entered into the present application. Claims 1 and 3 are currently amended. Claims 5 and 6 are withdrawn. Claims 1-4 are pending and are herein examined on the merits.

Applicant's arguments, filed March 17, 2008 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. Applicant adds new limitations to the claims that raise the issue of new matter. New matter issues are raised when Applicant includes limitations in the claims that he/she clearly did not have possession of at the time of invention. The silence of the disclosure regarding **to achieve maximum skin rest** and as a result of **at least one additional** incrementally decreasing amount of said neurotoxin is not sufficient to now claim the exclusion of such steps because nowhere in the disclosure has Applicant discussed **to achieve maximum skin rest** and the **at least one additional** incrementally decreasing amount of said neurotoxin in the context of the claimed method.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "to achieve maximum skin rest" is present. This phrase is vague and indefinite as to what "maximum skin rest" means. "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claim is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as

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the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (MPEP 2173).

The term "to achieve maximum" is a relative term, which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Because the term "to achieve maximum" would invite subjective interpretations of whether or not a particular ingredient amount is included by or excluded from the present claims, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims fail to meet either the tenor or express requirements of 35 U.S.C. 112, second paragraph and are properly rejected.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “effective amount” is present. This phrase is vague and indefinite as to what “effective amount” means. It is unclear as to what the amount is effective to achieve. The last 2 lines of claim 1 recites resting of the skin whereas the first line of claim 1 recites reducing the appearance of facial wrinkles. Therefore, the effectiveness of the amount confusingly is not defined as to whether it is controlled by the amount to reduce facial wrinkles or to rest the skin.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Donovan (PUB. NO. US2004/0009180 A1).

Donovan teaches a pharmaceutical composition for transdermal administration of neurotoxins, such as a botulinum toxin. The pharmaceutical compositions are topically applied on a patient (see abstract). A Botulinum toxin type A complex (BOTOX®) has been by the U.S. Food and Drug Administration for the treatment of blepharospasm, and treatment of glabellar wrinkles. Clinical effects of peripheral intramuscular botulinum toxin type A are usually seen within a day or a few hours after injection. The typical duration of symptomatic relief from a single intramuscular injection of botulinum toxin type A averages about three to four months (see paragraph 9). A commercially available botulinum toxin containing pharmaceutical composition is sold under the trademark BOTOX® (available from Allergan, Inc., of Irvine, Calif.). BOTOX® consists of a purified botulinum toxin type A complex (see paragraph 0018). Transdermal administration of pharmaceuticals has been the subject of research in attempt to provide an alternative route of administration of medications without undesirable consequences associated with injections and oral delivery. Needles often cause localized pain. Oral administration suffers from poor bioavailability of medications. Transdermal administration techniques attempt to overcome these shortcomings (see paragraph 40). A patient with bow furrows requests botulinum toxin to reduce the wrinkles. A suspension of BOTOX® is topically applied to the patient's forehead. In about 2-3 days, the patient begins to notice that the forehead wrinkles are reduced in number. At about 7 days, the wrinkles are gone. The effects of the BOTOX® last for about 4 months (see paragraph 91).

Reducing the BOTOX® treatment to zero BOTOX® is clearly a decreased

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amount as required in the instant claims for subsequent treatment. The instant claims do not exclude zero as a decreased treatment amount.

Consequently, the reference anticipates the claimed invention defined in claims 1-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanin et al. (US Patent No. 7140371 B2).

Hanin et al. teach in the present invention is based upon the discovery that a skin surface topographical method can be used to determine an effect of a Clostridial toxin or Clostridial neurotoxin upon a muscle. For example, the effect determined through use of the disclosed method can be a paralytic effect (i.e. inability to contract), including onset of effect, peak effect and duration of paralytic effect of a Clostridial toxin upon a muscle. Or, the effect determined may be a reduction in one or more characteristics of a wrinkle or wrinkles (see col. 10, lines 55-65). The botulinum neurotoxin of the first composition is a botulinum toxin type A also known as BOTOX®

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(see col. 14, lines 58-62). In view of the disclosure herein, a method of comparing botulinum neurotoxins or comparing effects caused by botulinum neurotoxins may comprise measuring a skin wrinkle at a location or region of an individual or measuring or otherwise quantifying one or more characteristics of such a skin wrinkle or skin wrinkles, administering a botulinum neurotoxin to a muscle in proximity to the skin wrinkle to reduce the wrinkle, and measuring the skin wrinkle at the location after administration of the botulinum neurotoxin. The method may be repeated for a second botulinum neurotoxin after the effects of the first botulinum neurotoxin have worn off (see col. 16, lines 8-23). After administration of the botulinum toxins, a second impression of the skin surface region is made while the first and second muscles are at a second maximum voluntary contraction. The first and second impressions are then examined and a skin wrinkle measurement is obtained (see col. 16, lines 38-42). The specific amount of a botulinum toxin administered depends upon a variety of factors to be weighed and considered within the discretion of the attending physician and in each of the examples insignificant amounts of botulinum toxin enter appear systemically with no significant side effects (see col. 17, lines 52-57). Dosages of the neurotoxin, such as botulinum toxin, in the compositions may vary. The compositions contain a therapeutically effective amount of neurotoxin, for example, between about 1 unit and about 500 units of botulinum toxin type A (see col. 17, lines 58-62). The patients' profiles and an administration schedule with a target end date is described in a clinical study for determining effect of a botulinum toxin upon a frontalis muscle (see col. 22, Example 4).

It would have been obvious to one skilled in the art to use the teachings of Hanin et al. to generate a method for reducing facial wrinkles by administering a therapeutically effective amount of botulinum toxin A. Therefore, one having ordinary skill in the art at the time of invention was made would have been motivated to use the teachings of the prior art cited above for a method of reducing facial wrinkles using botulinum toxin A as claimed in the present invention.

In the absence of any criticality/unexpected results presently claimed invention is considered *prima facie* obvious over the prior art for the reasons cited above.

Hanin et al. is supported by priority disclosures dating back to 3/14/2002.

Response to Argument

Applicant indicates that it has amended the language in claims 1 and 3 related to dosage amount to recite initial effective dosage amount is determined by the amount of neurotoxin composition required to achieve maximum skin rest based on the patient's diagnostic profile. It is still unclear as to what the amount is effective to achieve. The last 2 lines of claim 1 recites resting of the skin whereas the first line of claim 1 recites reducing the appearance of facial wrinkles. Therefore, the effectiveness of the amount confusingly is not defined as to whether it is controlled by the amount to reduce facial wrinkles or to rest the skin.

Applicant further indicates that Donovan does not describe multiple treatments with botulinum toxin type A to reduce wrinkles. Donovan very clearly states that the

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effects of the BOTOX® last for about 4 months. This means if the patient is need of more treatment will receive more than one treatment. Although Applicant has amended claims 1 and 3 to indicate at least one additional of said neurotoxin composition there is no support found in the specification for this amendment.

Applicant argues that Hanin III is not a prior art due to its date. Applicant is in error with the priority dates of Hanin. Hanin I, II, III has not changed the scope of its invention that is why they have filed continuation-in-part and the priority date was granted. Hanin I was totally relied on because it teaches injection of clostridial toxin such as botulinum toxin locally and directly into a target tissue such as intramuscular or subcutaneous injection. Further Hanin teaches botulinum toxin type A such as BOTOX to treat glabellar lines (brow furrows). This is the scope of the invention throughout of all the three inventions of Hanin's, therefore the argument that Hanin III is not a prior art is not persuasive.

Applicant further argues that none of the Hanins' disclose a method for multiple treatments of skin with a neurotoxin. Examiner does not agree, Hanin was not relied upon for multiple treatment of neurotoxin. Applicant is reminded that this is not an anticipation rejection this is an obviousness rejection where the secondary references are cited to reconcile the deficiencies of the primary reference. In obviousness rejection a combination of references is used, and the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish

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over the state of the art represented by the combination of the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725(CCPA 1968); *In re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Moreover, it is noted that rejections under 35 U.S.C. 103(a) are based on combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

For these reasons, and those already made of record at pages 3-7 of the previous Office Action dated October 18, 2007 of which such reasons are incorporated herein by reference, rejection of claims 1-4 remain proper and is **maintained**.

Applicant's amendments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

Conclusion

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner 1614

June 18, 2008

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614